

**REMARKS**

A new Figure 8 has been added to this application to improve the description. The description also has been amended to make reference to the new Figure 8 and to improve the description with respect to the subject matter of claim 35. Applicants have also explained that Figure 1 is a front view illustration of a face mask that is viewed in an upright position. This description corresponds to the subject matter in limitation (c) of newly-added claim 65 and 66.

In the Office Action mailed October 2, 2002, the Examiner indicated that claims 39 and 40 would be allowed if rewritten in independent form to include all the limitations of the base claim and any intervening claims. Applicants have presented a new claim 66 which includes much of the limitations of these claims. Accordingly, applicants particularly ask the Examiner to consider the allowability of the subject matter of claim 66 in a similar vein.

All of the claims pending in this application have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting. To overcome this rejection, applicants have enclosed a Terminal Disclaimer which disclaims the subject matter over copending application 08/240,877.

Claims 33, 44, 46, 49-50, 55-59, and 64 have been rejected under 35 USC § 103(a) as being unpatentable over Simpson in view of McKim. Applicants respectfully submit that these claims are patentable for the reasons presented in applicants' Amendment filed on June 25, 2002. In maintaining the rejection, the Examiner indicates that applicants' previously-submitted Castiglione Affidavit was disregarded "because there is no disclosure in Simpson et al. which suggests such a requirement." The requirement that the Examiner was referring to is the need for Simpson et al. to use negative inhalation pressure to maintain the flap in a closed position. Applicants respectfully submit that Simpson et al. does indeed provide such a disclosure. To demonstrate this, applicants have reproduced Figure 2 of the Simpson patent:

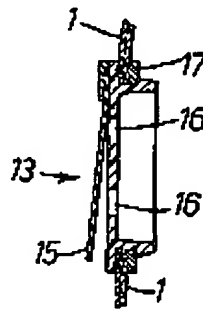


FIG. 2.

As this Figure shows, the Simpson flap 15 is not pre-stressed such that it would be pressed against the seal surface of the valve seat in a closed state of the exhalation valve. The exhalation valve therefore is placed on the top surface of the duck-billed mask as shown in Figure 1 of Simpson. In this position, the mask can rely on gravity to keep the flap pressed against the seal surface. But if the wearer tips their head downward and is not inhaling, the flap 15 can droop away from the seal surface and allow contaminants to enter the interior of the mask. The Simpson valve, however, is beneficial because it does prevent contaminants from entering the mask interior during the most important time, which is when the wearer inhales. The valve, nonetheless, is not able to prevent contaminant influx under the circumstance when the wearer tips their head fully downward and is not inhaling. The Examiner's reference to Figure 3 of Simpson is misplaced: that figure describes a button-style valve, which is not the subject matter of the present invention. And in any event, Simpson's button-style valve also is not pre-stressed.

As indicated above, applicants agree with the Examiner that Simpson's exhalation valve in Figure 2 "would remain in the closed position due to gravitational forces [when positioned on the mask as shown in Figure 1] until being subjected to the pressure of exhalation by a wearer." Applicants' pending claims, however, specify that the free portion of the flap is pressed towards or against the valve seat in a closed state of the exhalation valve *under any orientation of the valve*. Simpson's valve, however, only clearly remains in the closed position when the wearer does not have his/her head tilted downward. As previously indicated, Simpson's flap 15 could dangle open in response to gravitational forces when the mask is oriented such that the valve seat is not located beneath the flap.

The Examiner has also asserted that the Castiglione Affidavit is "insufficient" because the insertions made in it are not "based on actual physical inspection and comparison of the prior art

device to the device of the instant invention as claimed." The Examiner indicates that "actual objective testing of the prior art device" must to be done. This position is legally untenable under the law. Persons skilled in the respiratory art, particularly the exhalation valve art, like David M. Castiglione, are not required — and do not need — to test an actual exhalation valve to arrive at conclusions regarding how that device operates. The Simpson patent clearly shows a valve (in Figure 2) that does not have the flap 15 pre-stressed against the seal surface by virtue of how the flap is supported relative to the valve orifice. The valve shown in Simpson's Figure 2 has a flap-retaining surface that is in direct alignment with the seal surface. As such, the flap is not pre-stressed towards the seal surface. You do not need to test an actual sample of the device to come to this conclusion. A simple visual examination of the above-reproduced figure, with an understanding of basic physical principals (or perhaps even without), can allow one to easily recognize that Simpson's flap is not biased towards the seal surface.

The Examiner has stated that he did not find applicants' argument convincing that McKim is not analogous art. In so doing, the Examiner has maintained that McKim would have been "reasonably pertinent to the particular problem with which the applicant was concerned." In taking this position, the Examiner states that a person of ordinary skill would have looked at the McKim reference "to address problems associated with the effectiveness of valve seating of a valve element which is used for controlling the direction of flow of breathable air through such a valve." The Examiner explains that "McKim clearly addresses the problem of effectiveness of valve seating by nonaligning the flap-retaining surface and the seal surface to each other thereby providing effective seating without float or bounce after each opening (column 1, lines 64-72)." Applicants agree that the purpose of McKim is to solve the problem of float or bounce, exhibited by a reed valve in a two-cycle engine that operates at high rpms. But this purpose does not establish that McKim is analogous art. Indeed, it establishes the exact opposite. In order to show that a reference meets the second prong of the two-part analogous art test, the reviewing authority must consider **"the purposes of both the invention and the prior art"**<sup>1</sup> If the purposes are different, then the cited references should not meet the second prong of the two-part test for evaluating "analogousness".

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<sup>1</sup> *In re Clay*, 23 USPQ2d, 1058, 1061 (Fed. Cir. 1992).

**As applicants have previously explained — (with evidence in the form of Affidavits), — investigators who work in the field of exhalation valves for filtering face masks are not concerned with problems of float or bounce.** As explicitly stated by John Bowers in his Declaration, "under the airflows and pressure drops that are encountered in a filtering face mask 'bounce or float' is not an occurring event or problem that investigators in the exhalation valve art need to deal with." Thus, overcoming float or bounce is not a purpose of the present invention; nor is it a purpose or a desired goal in the development of any exhalation valve. The Federal Circuit has clearly stated that when the reference "is directed to a different purpose, the inventor would accordingly have less motivation or occasion to consider it" and therefore it would not be analogous.<sup>2</sup> **Accordingly, if the Examiner cannot establish that float or bounce is a problem that persons of ordinary skill in the exhalation valve art sought to overcome, McKim cannot be an analogous reference, and therefore the rejection based on McKim must be withdrawn.** Given the entirety of the record, it is clear that such evidence will not be forthcoming, and therefore this application must be allowed.

In *In re Clay*, the Federal Circuit found the cited reference to be not analogous when (1) the prior art taught the use of a gel within a natural, underground, oil-bearing formation (to channel flow in a desired direction) and (2) the applicant, Clay, had invented the use of a gel to fill the confined dead volume of a man-made storage tank. Although both Clay and the prior art (Sydansk) both described technology that related to the use of gels in the petroleum industry, *the Sydansk reference was found to be nonanalogous because the purpose of the Sydansk teachings were different from the purpose of the Clay invention.* Sydansk was faced with the problem of recovering oil from rock, which was not pertinent to the problem with which Clay was involved: namely, preventing loss of stored product in a tank's dead volume. The court also found that the subterranean formation of Sydansk was not structurally similar to and did not operate under the same temperature and pressure and did not function like Clay's storage tanks. As in *In re Clay*, the McKim reference also does not operate under the same temperature and pressure and does not function like the valve claimed in the present invention. Float or bounce is a problem that occurs when a two-cycle engine operates at high rpms (10,000 to 12,000 rpms). It is not a problem that occurs in an exhalation valve that opens and closes in cadence with a person's

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<sup>2</sup> *Id.*

breathing, which is about 20 to 60 cycles per minute. And internal combustion engines, of course, operate at extraordinarily higher temperatures and pressures than a person's exhalation breath and are not powered by a person's lungs but by the combustion of gasoline.

Applicants accordingly encourage the Examiner to carefully consider the *In re Clay* decision. A copy of this case is attached for ease of reference.<sup>3</sup>

In regard to applicants' statement that "no particular degree of flexibility is quantitatively and/or structurally defined in any of the claims of the instant application", applicants respectfully submit that this position is entirely incorrect. All of applicants' claims recite the use of a "flexible flap", and this term is explicitly defined in applicants' specification to mean that the flap "can deform or bend in the form of a self-supporting arc when secured at one end as a cantilever and viewed from a side elevation (see for example, Fig. 5)." Because this term has been explicitly defined, as quoted above, this definition must be used when evaluating the present invention in view of the prior art. Disregarding this definition or using any other term or meaning, is clear legal error.

As a final matter, the Examiner still has not provided the record with any evidence as to why a person of ordinary skill would have combined the teachings of Simpson and McKim. Therefore even if McKim was an analogous reference, which it clearly is not (since its purpose is entirely different from the purpose of the present invention and since it operates under extraordinarily different temperatures, pressures, and speeds, and is powered in an entirely

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<sup>3</sup> See also *SRI Int'l, Inc. v. Advanced Tech. Lab.*, 45 F.3d 443, 445 (Fed. Cir. 1995) ("The problem Green solved was how to compensate for changes in the spectral distribution of the return ultrasonic signal, with time or depth of penetration into a living organ, for enhanced image resolution and/or signal to noise ratio. The Minton reference, which relates to seismic prospecting circa 1946, almost thirty years prior to Green's filing date, would not have logically commended itself to Green's attention in considering how to compensate for changes in the spectral distribution of a received ultrasonic signal in an object such as a body part."); *In re Green*, 22 F.3d 1104, 1105 (Fed. Cir. 1994) ("A person of ordinary skill in the aircraft vane art simply would not find a 1919 reference about broken blades in a pugging mill reasonably pertinent to this problem."); *In re Butera*, 1 F.3d 1252, 1253, 28 USPQ2d 1399, 1400 (Fed. Cir. 1993) ("Butera's design is for air fresheners and insect repellents, while Hodge's is for metal ball anodes. The design of Hodge involves a different type of article from Butera's design and it is not analogous. One designing a combined insect repellent and air freshener would therefore not have reason to know of or look to a design for a metal ball anode. Since Hodge is not analogous, the Board clearly erred in finding Hodge to be citable as prior art. Therefore there was no basis for rejecting Butera's claimed design as obvious."); *Wang Laboratories, Inc. v. Toshiba Corp.*, 993 F.2d 858, 864, 26 USPQ2d 1767, 177\_ (Fed. Cir. 1993) ("Wang's SIMMs were designed to provide compact computer memory with minimum size, low cost, easy repairability, and easy expandability. In contrast, the Allen-Bradley patent relates to a memory circuit for a larger, more costly industrial controller. SRAMs were used by Allen-Bradley because of their intended industrial environment. According to Dr. Frey, size was not a consideration in the Allen-Bradley work. Thus, there is substantial evidence in the record to support a finding that the Allen-Bradley prior art is not reasonably pertinent and is not analogous.").

different manner), the Examiner still has the burden of showing that a person of ordinary skill would have been motivated to combine the teachings of Simpson and McKim. In previous Office Actions, the Examiner has again referred to the need for eliminating float or bounce as a reason for the motivation to combine the teachings. But once again the Examiner has not cited any authority for his view that eliminating float or bounce would be a problem that persons skilled in the art of designing exhalation valves would seek to overcome. Not only has the Examiner not provided the record with any evidence to support this position, the Examiner has also disregarded explicit evidence to the contrary, from an expert in the field of designing exhalation valves, John Bowers. The record is clear that float or bounce is not an occurring event or problem that is encountered by investigators in the exhalation valve art. Under such circumstances, any rejection based on Simpson and McKim cannot be properly sustained.

For the above reasons, and those previously presented in applicants' Amendment filed June 25, 2002, the prior art rejection based on Simpson and McKim must be withdrawn and this application should be allowed.

Respectfully submitted,

Date

1/2/03

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**Version with markings to show amendments made:****Page 6 amendments:**

FIG. 1 illustrates a front view of a filtering face mask 10 according to the present invention viewed in an upright position. Filtering face mask 10 has a cup-shaped mask body 12 to which an exhalation valve 14 is attached. Mask body 12 is provided with an opening (not shown) through which exhaled air can exit without having to pass through the filtration layer. The preferred location of the opening on the mask body 12 is directly in front of where the wearer's mouth would be when the mask is being worn. Exhalation valve 14 is attached to mask body 12 at the location of that opening. With the exception of the location of the exhalation valve 14, essentially the entire exposed surface of mask body 12 is fluid permeable to inhaled air.

**Page 15 amendments:**

Exhalation valve 14 can be provided with a valve cover to protect the flexible flap 24, and to help prevent the passage of contaminants through the exhalation valve. In FIG. 6, a valve cover 50 is shown which can be secured to exhalation valve 14 by a friction fit to wall 44. Valve cover 50 also can be secured to the exhalation valve 14 by ultrasonic welding, an adhesive, or other suitable means. Valve cover 50 has an opening 52 for the passage of a fluid. Opening 52 preferably is at least the size of orifice 32, and preferably is larger than orifice 32. The opening 52 is placed, preferably, on the valve cover 50 directly in the path of fluid flow 36 so that eddy currents are minimized. In this regard, opening 52 is approximately parallel to the path traced by the free end 38 of flexible flap 24 during its opening and closing. As with the flexible flap 24, the valve cover opening 52 preferably directs fluid flow downwards so as to prevent the fogging of a wearer's eyewear. All of the exhaled air can be directed downwards by providing the valve cover with fluid-impermeable side walls 54. Opening 52 can have cross-members 56 to provide structural support and aesthetics to valve cover 50. A set of ribs 58 can be provided on valve cover 50 for further structural support and aesthetics. Valve cover 50 can have its interior fashioned such that there are female members (not shown) that mate with pins 41 of valve seat 14. As shown in FIG. 8, [V] valve cover 50 also can have a surface 59 [(not shown)] that holds flexible flap 24 against flap-retaining surface 40. The valve cover 50, when secured to the valve seat 26, defines an internal chamber into which the flap-retaining surface is located. Valve cover 50 preferably has fluid impermeable ceiling 60 that increases in height in the direction of the flexible flap from the fixed end to the free end. The interior of the ceiling 60 can be provided with a ribbed or coarse pattern or a release surface to prevent the free end of the flexible flap from adhering to the ceiling 60 when moisture is present on the ceiling or the flexible flap. The valve cover design 50 is fully shown in U.S. Design Patent Application 29/000,382. Another valve cover that also may be suitable for use

on a face mask of this invention is shown in Design Patent Application 29/000,384. The disclosures of these applications are incorporated here by reference.